FEB 2 7 2013

510(K) Summary

CarboFix Orthopedics Ltd.

Piccolo Composite® Plate System

Applicant Name

CarboFix Orthopedics Ltd.

11 Ha'hoshlim St., Herzeliya 46724, Israel

Contact Person

Yael Rubin

CarboFix Orthopedics Ltd.

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Tel: +972 9 9511511, Fax: +972 9 9548939

Date Prepared

January 2013

Trade/Proprietary Name

Piccolo Composite® Plate System

Common Name

Plating System

Classification Name

Single/multiple component metallic bone fixation appliances and accessories (21 CFR §888.3030; Product Code HRS)

Smooth or threaded metallic bone fixation fastener (21 CFR §888.3040; Product Code HWC)

Predicate Devices

- Piccolo Composite® Plate System (CarboFix Orthopedics Ltd.); K102597, K120409)
- Members of the Synthes Locking Compression Plate System (Synthes; *e.g.*, K000682, K082807)

Intended Use/Indications for Use

Piccolo Composite Plate System - Diaphyseal

The Piccolo Composite Diaphyseal Plate is indicated for the fixation of various long bones, such as the humerus, femur and tibia, including osteopenic bone, osteotomies, and nonunions or malunions in adult patients.

These plates are also indicated for fracture fixation of diaphyseal areas of long bones in pediatric patients.

System Description

The Piccolo Composite Plate System comprises implants (plates and screws), and a set of instruments.

The plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with a tantalum thread, to provide for their visualization under fluoroscopy.

The Piccolo Composite Diaphyseal Plate is either 4.5mm, 5mm, or 5.3mm thick; 14.5mm or 17.5mm wide; and is provided in lengths of 82 – 220mm (4 – 13 holes), depending on plates thickness and width.

The screws are made of titanium alloy. Both locking (Ø4.0mm and Ø5.0mm) and non-locking (Ø4.5mm) screws are available in a range of lengths.

Substantial Equivalence

The Piccolo Composite Nailing System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Performance characteristics for the Piccolo Composite Diaphyseal Plate System, such as single cycle (static) 4-point bending and dynamic (fatigue) 4-point bending, were evaluated per ASTM F 382 – Standard Specification and Test Method for Metallic Bone Plates and are comparable to those of predicate devices (where applicable). Selected screws characteristics evaluation was also performed. All the above demonstrate that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Carbofix Orthopedics, Ltd.
% Ms. Yael Rubin
Director of Regulatory Affairs
11 Ha'Hoshlim Street
46724 Herzeliya
Israel

Re: K130061
Trade/Device Name: Piccolo Composite® Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories.
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 27, 2013
Received: January 31, 2013

Dear Ms. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K130061

Device Name: Piccolo Composite® Plate System

Indications for Use:

Piccolo Composite® Plate System - Diaphyseal

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Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices